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International application number: PCT/CA05/000635

International filing date: 26 April 2005 (26.04.2005)

Document type: Certified copy of priority document

Document details: Country/Office: US
Number: 60/564,963
Filing date: 26 April 2004 (26.04.2004)

Date of receipt at the International Bureau: 26 May 2005 (26.05.2005)

Remark: Priority document submitted or transmitted to the International Bureau in compliance with Rule 17.1(a) or (b)

PA 1298722

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APPLICATION NUMBER: *60/564,963*
FILING DATE: *April 26, 2004*

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PTO/SB/16 (06-03)
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# PROVISIONAL APPLICATION FOR PATENT COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c).

Express Mail Label No.

## INVENTOR(S)

| Given Name (first and middle (if any)) | Family Name or Surname | Residence (City and either State or Foreign Country) |
|---|---|---|
| Benoît | CHOUINARD | Montréal, Québec, Canada |

☐ Additional inventors are being named on the ____ separately numbered sheets attached hereto

## TITLE OF THE INVENTION (500 characters max)

METBOD FOR PERMANENT CALIBRATION BASED ON ACTUAL MEASUREMENT

## CORRESPONDENCE ADDRESS

Direct all correspondence to:

☒ Customer Number 020988

OR

☐ Firm or Individual Name

Address

Address

City | State | ZIP

Country | Telephone | Fax

## ENCLOSED APPLICATION PARTS (check all that apply)

☒ Specification *Number of Pages* 9 ☐ CD(s), Number

☒ Drawing(s) *Number of Sheets* 3 ☐ Other (specify)

☐ Application Data Sheet, See 37 CFR 1.76

## METHOD OF PAYMENT OF FILING FEES FOR THIS PROVISIONAL APPLICATION FOR PATENT

☐ Applicant claims small entity status. See 37 CFR 1.27

☐ A check or money order is enclosed to cover the filing fee

☒ The Director is hereby authorized to charge filing Fees or credit any overpayment to Deposit Account Number: 19-5113

☐ Payment by credit card. Form PTO-2038 is attached

FILING FEE AMOUNT ($): 160.00

The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government.

☒ No.

☐ Yes, the name of the U.S. Government agency and the Government contract number are: _____

[Page 1 of 1]

*Respectfully submitted,*

SIGNATURE

TYPED or PRINTED NAME Pierre T. NGUYEN

TELEPHONE (514) 847-4243

Date April 26, 2004

REGISTRATION NO. *If appropriate)* 55,043

Docket Number: 15228-39uspr PTN/df

15228-39USPR
OS-58USPR

# METHOD FOR PERMANENT CALIBRATION BASED ON ACTUAL MEASUREMENT

## FIELD OF THE INVENTION

[0001] The present invention generally relates to instrumentation and, more particularly, to a method for marking the characteristics of an instrument used in a computer-assisted surgery environment.

## BACKGROUND OF THE INVENTION

[0002] Instruments and implants, like surgical instruments and orthopedic implants are manufactured according to manufacturing drawings. The manufacturing drawings are specifying dimension precision of the manufactured instruments. These dimension precisions are required when the instruments or implants are used in a precision environment. Such an environment is encountered in a Computer Assisted Surgery (CAS) system.

[0003] After the manufacturing of an instrument, comparative measurements of the manufactured instrument are made with the manufacturing drawings. If the end result of the measurements is outside the specifications of the manufacturing drawings, the instrument is rejected. To achieve a high precision manufacturing process is expensive.

[0004] A CAS system creates a precision environment where a surgeon uses a computer system to track, in a 3-dimensional reference spatial system, one or more instruments and implants. The precision required varies from 0.1 mm to 1 mm. The instruments and implants tracked by the CAS system have generic characteristics that need to be known by the CAS system. The CAS system needs to track the geometrical characteristics of an instrument or an implant. The CAS system needs the geometrical characteristics of the tracked instruments as well as the relative position of the

implant/tool on the instrument to the tracker coordinate system.

[0005] There exist two calibration methods. The first one consists in identifying the tip and the axis of a tool with the help of a calibration block. The block has a base plate with a pin hole located at its center to position the tip of the instrument. Around the pin hole, eight posts are placed in a quasi-circular position. The tool is equipped with a means for registering and tracking the tool is a 3D environment. For registering the tip of the instrument, the tip is positioned against the pinhole located at the center of the base plate. The system registers both the calibration block and the instrument and extrapolate the tips of the instrument from it position in the pinhole of the calibration block. To determine the axis, the instrument is successively positioned against the eight posts located on the calibration block and registered. A second method consists in a simplified calibration block capable of position the tool against a reference pinhole and clamp in a known position. The system registers both the calibration block and the instrument. From the registration of the tool, the system can extrapolate the position of the tip and, since the calibration block has clamped the instrument in a know position, the system can extract the axis of the tool from the registration of the tool and the calibration block and the known position of the clamped instrument.

[0006] More specifically, in a hip or knee replacement surgery, an instrument like a registration pointer will be used to identify specific area of the anatomy of the patient. The manufacturing process of surgical instruments follows precise indication included on the manufacturing drawings. Once the tool is manufactured, verification measurements are made for comparison with the manufacturing drawing. The measurements verification implies a high rejection level and, consequently, a high cost of

production. The tools that satisfy the measurements verification are used in operating room. The first step is to calibrate the tool. Accordingly, it would be advantageous to have a method for instrument manufacturing process that is simple and highly precise and eliminates the calibration when in use in the operating room.

[0007] Alternatively, it may be desired to have a method for identifying an instrument and obtaining the accurate measurement without involving extra manufacturing cost.

## SUMMARY OF THE INVENTION

[0008] Accordingly, an object of the present invention is to provide a novel method for permanent calibration based on actual measurement.

[0009] Therefore, in accordance with the present invention, there is provided a method for identifying a device being used with a CAS system, said CAS system defining a high precision environment for using said device and said CAS system having a database of stored part of the geometrical device's characteristics , said method comprising the steps of accurately measuring characteristics of said device; translating said accurate measurements in a machine readable format; marking said device with said translated machine readable format; reading said accurate measurements marked on said device by said CAS system; and adjusting said device's stored characteristics to be used by said CAS system.

[0010] Further in accordance with the present invention, there is provided a device for using in a high precision environment, said device comprising a set of defined characteristics, wherein said defined characteristics being accurate measurements of said device; and a translation of said precise measurements to machine readable format, wherein said translation is marked onto said device.

[0011] Still further in accordance with the present invention, there is provided a system for using a device in a high precision environment, said system comprising a computer; a reader connected to said computer, said reader being capable of reading data translated in machine readable format, wherein read machine readable format data is transmitted to said computer; and said device having precise characteristics, said precise characteristics being translated to machine readable format, wherein said machine readable format data is marked on said device.

[0012] Still further in accordance with the present invention, there is provided a system for using a device in a high precision environment, said system comprising: a computer, said computer having a database storing precise characteristics of said device, wherein said computer uses said precise characteristics of said device in said high precision environment; and a data entry apparatus for inputting of data, said data entry connected to said computer and said data entry apparatus transmitting input data to said computer, wherein said data entry is a device identification transmitted to said computer.

## BRIEF DESCRIPTION OF DRAWINGS

[0013] These and other features, aspects and advantages of the present invention will become better understood with regard to the following description and accompanying drawings wherein:

[0014] Fig. 1 is a view of an instrument with exemplary machine readable format marking;

[0015] Fig. 2 is a process diagram implementing the preferred embodiment of the present invention;

[0016] Fig. 3 is a view of the system, in accordance with a preferred embodiment of the present invention;

[0017] Fig. 4 is an example of a linear bar code; and

[0018] Fig. 5 is an example of a 2-dimensional matrix bar code.

**DESCRIPTION OF THE PREFERRED EMBODIMENT**

[0019] In a preferred embodiment of the present invention, at the end of the manufacturing process, the characteristics of the instrument needed by a CAS system are precisely measured. Those measurements, unique to that instrument, are recorded on a media and constitute the permanent calibration of that instrument. At the first use in an operating room, the instrument is selected and those measured characteristics are fed to a CAS system which can store the information. At further use, the operator can select the instrument per its identification and the system can use the stored information or read again the information related to the characteristics of the instrument.

[0020] Referring to the drawings and, more particularly, to Fig. 1, an instrument 130 with exemplary marking 132 is showed. The instrument 130 is manufactured according to manufacturing drawings containing measurement specifications and precision. Once the instrument 130 is manufactured, accurate measurements of the instrument are done using for instance a Coordinate Measuring Machine (CMM), which permit a precision as high as 0,001mm. Those measurements represent characteristics of the instrument 130 to be used in a precision environment. The marking 132 on the instrument 130, is made on a section visible to the operator.

[0021] Alternatively, typographic characters readable (not showed) by a video system and identifiable by a computer system can be used.

[0022] The content of marking 132 can consist of an identification of the instrument consisting of a product code, a serial number for tracking inventory or measurements made to a specified degree of precision.

[0023] Fig. 2 relates to the process used to implement the preferred embodiment of the present invention.

[0024] In step 200, an instrument is manufactured according to the manufacturing drawings. Those manufacturing drawings specify dimensions for the instrument with lax tolerances. At step 210, the characteristics (dimension, plane) of the manufactured instrument required by the system are accurately measured or defined. Those accurate measurements are converted to machine readable format at step 220. Then, at step 230, the converted measurements are marked onto the instrument. That process reduces the cost of manufacturing, permits the use of the instrument in a high precision environment, eliminates the calibration previously required and can result in a higher precision of the CAS system. To properly ensure the tool registered, a validation step is used (not showed on the figure). When a tool is used by the CAS system, to validate the information marked on the tool in relation to the physical tool, the system would validate the position of the marker in relation to an extremity of the tool.

[0025] Fig. 3 shows a system using the instrument illustrated in Fig. 1. The system is used for identifying an instrument in a high precision environment is generally shown at 310. A computer 312, comprising a database 314 is showed. That database contains part of the geometrical characteristics of the instruments. The information needs to be completed with the results of measurement taken in step 210 in order to take in account the small variations from one instrument to another. The computer 312 can be part of a CAS system (not showed). The computer 312 is connected, through link 318, to a reader 316.

[0026] The reader 316 can be mechanical, optical, electromagnetic or other type generally known in the art of the reader capable of reading machine code format.

[0027] The machine readable format is known in the art as bar code. The bar code format can be a linear format or a 2-dimensional matrix bar code permitting higher data density marking.

[0028] The instrument 320 is marked with machine reader format data 324. The data 324 marked on the instrument 320 contains characteristics of the instrument 320. These characteristics relate to identification of the instrument and accurate dimension of the instrument 320 measured after manufacturing.

[0029] When the data 324 is read by the reader 316 on the instrument 320 and transmitted to computer 316, computer 316 identifies the instruments. It can get generic characteristics about the instrument 320 from the database 314. With the accurate measurement read from the machine reader format data 324, the computer 316 can adjust the characteristics of instrument 320.

[0030] Another method for entering the data to be marked on the instrument is through manual data entry. The data related to the serial number of the instrument and the measured characteristics are keyed into a device capable of converting to a machine readable format. That converted data is then marked onto the instrument.

[0031] As another method the instrument 320 can be packaged with a CD-ROM or another storage media containing the characteristics of the instrument it is to be understood that database 314 can be a temporary storage media and not necessarily a permanent database.

[0032] As another alternative the database 314 can be remotely accessed through a communication means.

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**CLAIMS:**

1. A method for identifying a device being used with a CAS system, said CAS system defining a high precision environment for using said device and said CAS system having a database of stored part of the geometrical device's characteristics , said method comprising the steps of:

accurately measuring characteristics of said device;

translating said accurate measurements in a machine readable format;

marking said device with said translated machine readable format;

reading said accurate measurements marked on said device by said CAS system; and

adjusting said device's stored characteristics to be used by said CAS system.

2. A device for using in a high precision environment, said device comprising:

a set of defined characteristics, wherein said defined characteristics being accurate measurements of said device; and

a translation of said precise measurements to machine readable format, wherein said translation is marked onto said device.

3. A system for using a device in a high precision environment, said system comprising:

a computer;

a reader connected to said computer, said reader being capable of reading data translated in machine readable format, wherein read machine readable format data is transmitted to said computer; and

said device having precise characteristics, said precise characteristics being translated to machine readable format, wherein said machine readable format data is marked on said device.

4. A system for using a device in a high precision environment, said system comprising:

a computer, said computer having a database storing precise characteristics of said device, wherein said computer uses said precise characteristics of said device in said high precision environment; and

a data entry apparatus for inputting of data, said data entry connected to said computer and said data entry apparatus transmitting input data to said computer, wherein said data entry is a device identification transmitted to said computer.

5. A system for using a device in a high precision environment as described in claim 4, wherein said database is stored on a storage media.

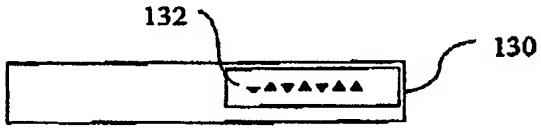


Fig. 1

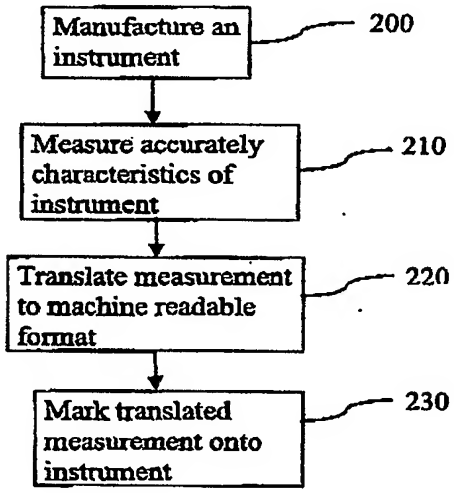


Fig. 2

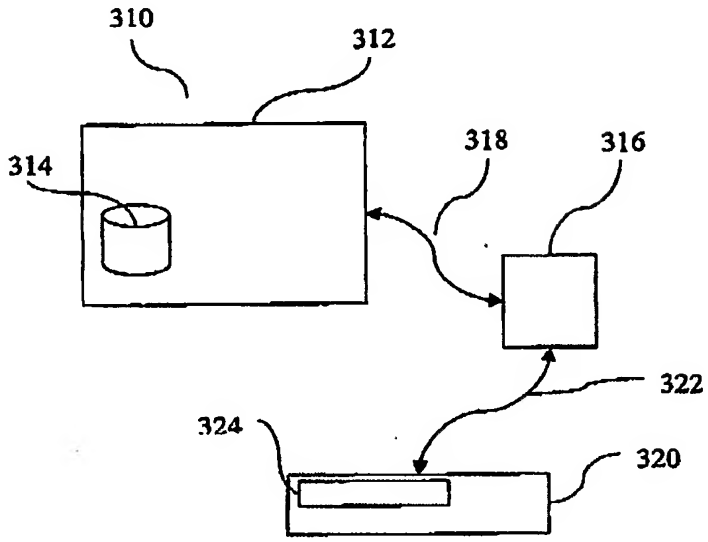


Fig. 3

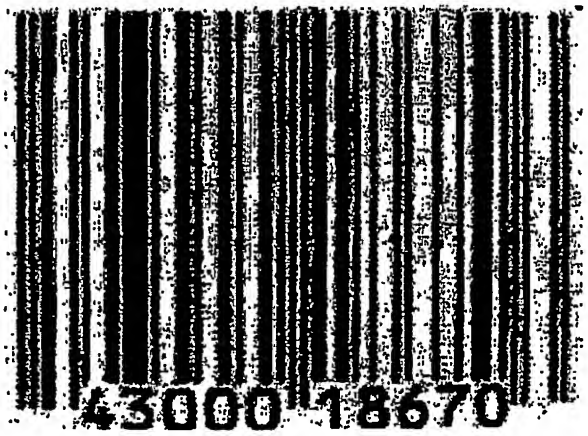


Fig. 4

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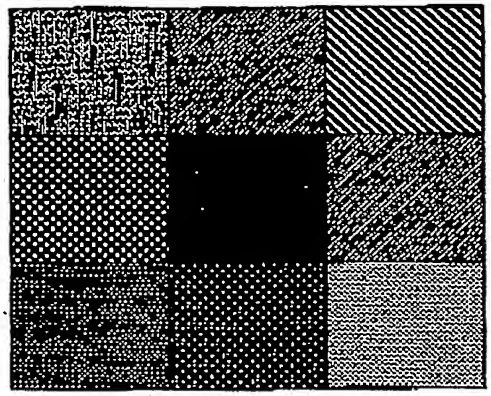
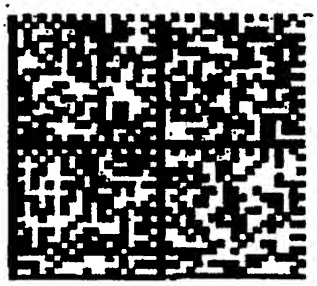


Fig. 5



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